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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,965	01/22/2004	Xudong Huang	0492479-0033 (MGH 2231)	6347

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,965	HUANG, XUDONG	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/24/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-174* is/are pending in the application.

4a) Of the above claim(s) *96-122 and 143-170* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *123-142 and 171-174* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 10/24/06 wherein the specification was amended; claims 1-95 are canceled; 123-125, 128, 135, and 136 are amended; and claims 171-174 are added.

Note: Claims 96-174 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 10/24/06 to the rejection of claims 123-142 made by the Examiner under 35 USC 102, 112, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Double Patenting Rejection

The provisional rejection of claims 123-142 and 171-174 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 10-12, and 32 of copending application number 11/096,919 is MAINTAINED for reasons of record in the office action mailed 6/21/06.

Note: It is duly noted that Applicant intends to respond to the provisional rejection when the rejection matures into an actual rejection.

112 Second Paragraph Rejection

The 112 rejection is WITHDRAWN because Applicant has amended the claim to overcome the rejection.

102 Rejection

The 102 rejection is WITHDRAWN because Applicant has amended the claim to overcome the rejection.

WITHDRAWN CLAIMS

3. Claims 96-122 and 143-170 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

NEW GROUNDS OF REJECTION

103 Rejection

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 123-125 rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al (US Patent No. 6,329,531).

Turner et al disclose optical diagnostic agents having formula (I), Fm(-A1)(-Bn)(-Wo) wherein A is an amyloid plaque binding biomolecule and 1 independently represents the numbers 0, 1, or 2 (see entire document, especially, abstract; column 2, lines 41-54). Possible biomolecules include antibodies, antibody fragments, peptides, proteins, receptors, enzymes, nucleotides, ribonucleic acids, deoxyribonucleic acids, carbohydrates and saccharides (see column 6, lines 20-67). Thus, while Turner et al fail to disclose a diagnostic agent having multiple amyloid binding biomolecules, a skilled practitioner in the art would be motivated to have at least two amyloid binding

molecules because Turner et al disclose that two amyloid plaque binding biomolecules may be present in their formula.

6. Claims 123-125 rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al (US Patent No. 6,329,531) in view of Gervais et al (US 2002/0115717).

Turner et al (see discussion above) fail to disclose the a chelating agent in combination with multiple amyloid binding moieties.

Gervais et al disclose amyloid targeting imaging agents and uses thereof. In particular, Gervais et al disclose amyloid targeting imaging agents such as radiolabeled amyloid targeting molecules and amyloid targeting molecule chelator conjugates for imaging amyloid plaques in vivo and/or for the treatment of amyloidosis disorders (see entire document, especially, abstract). The amyloid targeting imaging agents may be of Formula, At-(Alnk)z-Alab wherein At is an amyloid targeting moiety; Alnk is a linker moiety; and Alab is a labeling moiety (page 2, paragraph [0010]. The labeling moiety, Alab, may be a metal chelate (a chelate of a metal with a ligand of Formula VII). In an advantageous embodiment, Alab includes a radionuclide. In cases where the amyloid targeting imaging agent includes a labeling moiety Alab (including a radionuclide) attached directly to amyloid targeting moiety At, and linker moiety Alnk is optional (page 3, paragraph [0035]). Labeling moieties Alab may include diagnostically or therapeutically useful radionuclides such as 3H, 129I, 125I, 131I, or 18Fe for use as radiopharmaceuticals. In one embodiment, the labeling moiety Alab includes Tc or Re. The labeling moiety Alab may also be a combination of radionuclide(s) and a metal

chelator (page 3, paragraph [0036]). The labeling moiety may be an echogenic substance in the case of an ultrasound contrast agent; a paramagnetic metal chelate in the case of an MRI contrast agent; a radioactive atom (e.g., radioactive fluorine) or a chelated radioactive metal ion (e.g., In-111) in the case of a radionuclide imaging agent; a radio-opaque chelate or compound (e.g., a polyiodinated aromatic) for an x-ray contrast agent; or a fluorescent or colored dye in the case of an optical imaging contrast agent. In one embodiment labeling moiety Alab may be a metal chelator (page 14, paragraph [0156]). The selection of radionuclides include Tc-99m, Re-186, In-111, and Ga-67 (page 14, paragraph [0159]). In a particular embodiment, the labeling moiety, Alab, includes 129I, 125I, 131I, or 18F (page 15, paragraph [0161]). One aspect of Gervais et al involves an amyloid targeting molecule chelator conjugate of Formula VII (page 15). May chelators such as DTPA may be utilized (page 15, paragraph [0164]). The imaging compositions which target amyloid in vivo are capable of crossing the blood brain barrier to allow imaging (page 8, paragraphs [0092] – [0094]. Preferred) include those that have specificity for Aβ amyloid deposits (page 8, paragraphs [0108] and [0109]; pages 9-10, SEQ ID Nos. 1-49). Pharmaceuticals comprising the compounds/compositions of the instant invention may be formulated with a variety of counter ions/carriers (page 12, page [0142]; page 16, paragraph [0172]). Contrast agents such as a peptide targeting moiety conjugated to DTPA is typically reacted with GdCl3 or Gd2O3 (page 17, paragraph [0177]).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Turner et al using the teachings of Gervais et al and

conjugate a chelating moiety to the amyloid binding moieties. In particular, since Gervais et al disclose that it is known in the art to having an amyloid binding moiety conjugated to a chelating moiety, a skilled artisan would be motivated to attach multiple amyloid targeting moieties because one would recognize that multiple diseases or targeting sites may be sought.

COMMENTS/NOTES

7. It should be noted that Applicant's elected Group VII (claims 123-142 and newly added claims 171-174) are being examined.

8. It should be noted that claims 135, 142, and 171-174 are free of the prior art of record because the prior art neither anticipates nor renders obvious the imaging agent as set forth in independent claim 135. However, Applicant MUST address and overcome the double patenting rejection above.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

January 22, 2007